NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, et al., *EX REL.* JOSEPH PIACENTILE, Plaintiff, v.	Civ. Action No. 05-2927 (KSH)
SANOFI SYNTHELABO, INC. and AVENTIS PHARMACEUTICALS, INC., Defendants.	**OPINION**

KATHARINE S. HAYDEN, U.S.D.J.

I. Introduction and Statement of Facts

Joseph Piacentile ("Piacentile"), the plaintiff in this action, brings claims under the federal False Claims Act ("FCA"), as well as numerous state false claims acts. Underlying his claims are three related courses of conduct by the defendants, Aventis Pharmaceuticals, Inc. ("Aventis") and Sanofi Synthelabo, Inc. ("Sanofi"), to increase their profits and market share, allegedly through improper means. The defendants move to dismiss Piacentile's Second Amended Complaint [D.E. 35].

For the purposes of deciding the motion, all of the facts alleged in the complaint and all reasonable inferences that can be drawn therefrom are accepted as true. See Great W. Mining & Mineral Co. v. Fox Rothschild LLP, 615 F.3d 159, 161 (3d Cir. 2010).

A. Aventis' Off-Label Marketing

Aventis is a pharmaceutical manufacturer based in New Jersey whose products include Taxotere, a cancer drug. (Second Am. Compl. ¶¶ 21–22, 54.) Before May 2004, Taxotere was only approved for treating advanced forms of breast and lung cancer. (*Id.* ¶ 54.) On May 19, the drug was approved for treating advanced prostate cancer, and on August 19, 2004, it was approved for treatment of operable, early stage breast cancer. (*Id.* ¶ 55.) Despite the fact that Taxotere's approved uses were limited, Aventis's sales force promoted to doctors so-called off-label uses of the drug—uses the FDA had not approved. Former Aventis sales representatives told Piacentile that Aventis employed 30 managers whose sole purpose was to promote off-label uses of Aventis drugs. (*Id.* ¶¶ 64–65.) Once an Aventis drug is approved for a previously off-label use, the salespeople move on to promote another off-label use. (*Id.* ¶ 67.)

Aventis sponsored educational conferences to discuss off-label uses, and they invited high-prescribing physicians to these events. (*Id.* ¶¶ 61–62.) Though the conferences were purportedly educational, they were in actuality commercial promotional events which physicians are paid to speak at and attend, and which were used by Aventis salespeople to promote the off-label use of Taxotere and other Aventis drugs. (*Id.* ¶ 66.) In particular, one of the Aventis salespeople Piacentile spoke to said that Dr. Paul Kline of St. Vincent's Hospital in New York City was paid to give presentations on off-label uses of Taxotere; sales representatives then targeted attendants of these presentations to promote Taxotere's off-label uses. (*Id.* ¶ 82.) In addition, Aventis arranged for Drs. Clifford A. Huddis and Naiyer A. Rizvi of Memorial Sloan-Kettering Cancer Center to give presentations and assist Aventis's off-label marketing efforts. (*Id.* ¶ 83.) Aventis's Taxotere market share at Sloan-Kettering then doubled within one year. (*Id.*) According to the complaint, whenever a physician or medical institution submitted a claim

to a government program for reimbursement for an off-label use that Aventis had promoted, a false claim was submitted in violation of the FCA. (*Id.* ¶ 78.)

B. Aventis's Kickback Scheme

Piacentile alleges that Aventis conducted a three-pronged kickback scheme, under which it provided physicians with money, property, and services to induce them to prescribe Aventis drugs, including Taxotere and Anzemet, which is used to control nausea induced by chemotherapy. (*Id.* ¶ 56.)

First, Piacentile alleges that Aventis paid doctors money to induce prescriptions. Aventis salespeople had budgets of up to $36,000, referred to as a "martini budget," to use induce doctors to prescribe Aventis drugs. (*Id.* ¶ 91.) Aventis also paid a handful of high-prescribing physicians more than $2,000 each year to speak at lavish dinners attended by other physicians and tailored sham research grants to physicians as rewards for prescribing the company's drugs. (*Id.* ¶ 92–93.) One physician who received a grant was Huddis; Piacentile claims that Huddis helped to increase Sloan-Kettering's purchases of Taxotere from 170 vials per month to nearly 400 vials per month, mostly for off-label use. (*Id.* ¶ 94.) Drs. Mark Kris and Nadir Rizby of Sloan-Kettering, and Dr. Michael Kane of the Cancer Institute of New Jersey also received grants, and Dr. Kline received $3,500 to give her presentations. (*Id.* ¶¶ 95, 97.) In addition, Aventis maintains lists of doctors who use Aventis drugs off-label and pays them between $750 and $1,000 to attend conferences where such uses are discussed. (*Id.* 98–99.) According to the complaint, whenever a physician who had received money from Aventis submitted a claim to the government seeking reimbursement for an off-label use, a false claim was submitted in violation of the FCA. (*Id.* ¶ 104.)

Second, Piacentile alleges that Aventis provided millions of dollars of free drugs to physicians, including free samples and overfilled vials, to induce them to prescribe Aventis drugs. According to Piacentile's sources, 116 Aventis sales representatives each provided up to 1,200 free samples a year, totaling more than $50 million in market value over a five-year period. (*Id.* ¶ 108.) Aventis also provided doctors with vials of product that exceeded the necessary dosage, which doctors then used on other patients; this extra product totaled more than 100 vials per month. (*Id.* ¶ 109.) One salesman told Piacentile that he gave Dr. Richard Burke of Mount Sinai Hospital free samples for 15 to 20 patients and that Burke could collect $30,000 on each of these samples by billing Medicare and Medicaid for them. (*Id.* ¶ 110.) The salesman also provided free samples to oncologists at Salick Health Care, including Dr. Arthur Goldberg and Dr. William Grace. (*Id.* ¶ 111.) Aventis also gave discounts to health care formulary groups based on Aventis's market share of the groups' prescriptions. (*Id.* ¶ 112.) Dr. Burke brought $750,000 per year to Aventis in Anzemet sales from Mount Sinai, and both Drs. Goldberg and Grace increased their use of Anzemet. (*Id.* 113.) According to the complaint, each time one of these doctors sought reimbursement from the government for Anzemet, a false claim was submitted. (*Id.*)

Third, Piacentile alleges that Aventis provided free services to doctors, including practice management consulting services and lessons in how to mix Taxotere and Anzemet prescriptions to "get the most out of the vials" by capturing excess product. (*Id.* ¶¶ 117–19.) According to the complaint, each time a doctor received free services from Aventis and then sought reimbursement for Aventis drugs from the government, a false claim was submitted. (*Id.* ¶ 122.)

C. Sanofi's Kickback Scheme

Sanofi is also a manufacturer of pharmaceuticals[1]; relevant to this motion, it produces Plavix, which is used to reduce the risk of heart attack, stroke, or vascular death associated with arterial disease, and Avapro, which is used to treat hypertension. (*Id.* ¶¶ 57–58.) Piacentile interviewed a Sanofi marketing representative who told him that sales representatives selected approximately 165 high-prescribers of Sanofi drugs for inclusion on lists of speakers for drug symposia. (*Id.* ¶¶ 135–137.) The selected doctors were paid between $1,000 and $2,000 for each speaking engagement. (*Id.* ¶ 138.) The sales representatives were given $36,000 a year to give as rewards to high-prescribing physicians. (*Id.*) Sanofi also provided $100 educational grants to doctors to attend lectures and lavish dinners and to prescribe Sanofi drugs, and it sometimes gave direct payments to speakers, which it classified as honoraria. (*Id.* ¶ 139.) According to the salesperson, one-third of his list of physician contacts sold Sanofi products due to Sanofi's inducements. (*Id.* ¶ 140.) In particular, Sanofi paid Dr. Michael Schloss for prescribing Avapro and paid Dr. Allen Unger between $1,000 and $2,500 to invite his colleagues to lavish dinners at which Dr. Unger discussed Plavix. (*Id.* ¶¶ 141–42.) According to the complaint, each time a doctor who had been paid by Sanofi submitted a claim for reimbursement for an off-label prescription for Sanofi drugs, a false claim was submitted. (*Id.* ¶ 147.)

II. Discussion

Piacentile filed the instant action as a *qui tam* relator under 31 U.S.C. § 3730(b), which provides that a private person may bring an action on behalf of the government to enforce the FCA. He alleges violations of 31 U.S.C. § 3729(a)(1) (presentation of false claims), § 3729(a)(2) (making or using a false record or statement to cause a claim to be paid), § 3729(a)(7) (making or using a false record or statement to avoid an obligation to refund), § 3729(a)(3)

[1] Indeed, Aventis's parent corporation, Aventis SA, and Sanofi's parent corporation, Sanofi Synthelabo SA, merged in 2004 to become Sanofi-Aventis Group S.A. (Second Am. Compl. ¶ 21.)

(conspiracy), and numerous state false claims acts. The defendants have moved to dismiss on three grounds: (1) Piacentile's claims against Aventis regarding Anzemet and Taxotere are barred by the FCA's first-to-file rule; (2) the complaint fails to state a claim under Fed. R. Civ. P. 12(b)(6); (3) the complaint fails to plead fraud with particularity under Rule 9(b). Because the Court finds that the first-to-file rule bars Piacentile's claims regarding Anzemet and Taxotere, and that the complaint fails to plead fraud with particularity, it will not address the defendants' 12(b)(6) arguments.

A. The FCA's First-to-File Bar

1. The First-to-File Bar Applies in This Case

The defendants argue that Piacentile's claims against Aventis regarding its promotion of Taxotere and Anzemet are barred by the FCA's "first-to-file" rule. They claim that a relator named Yoash Gohil filed an FCA claim against Aventis on May 17, 2002, in the Eastern District of Pennsylvania, alleging substantially the same facts that underlie Piacentile's claims against Aventis. (Opp'n Br. at 6; *United States ex rel. Gohil v. Aventis Pharms., Inc.*, Civil Action No. 02-CV-2964 (E.D. Pa.)). Because Piacentile did not file his initial complaint until June 7, 2005 [D.E. 1], the defendants claim he cannot bring his claims against Aventis at all.

Section 3730(b)(5) provides that "[w]hen a person brings a[] [*qui tam* action], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." This "first-to-file bar" is "exception free," *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001), and a court must "judge whether § 3730(b)(5) barred [a] *qui tam* action by looking at the facts as they existed at the time that action was brought." *Grynberg v. Koch Gateway Pipeline Co.*, 390 F.3d 1276, 1279 (10th Cir. 2004.) In *Lujan*, the Ninth Circuit held that an earlier-filed complaint that was eventually dismissed

after a subsequent complaint was filed nevertheless barred the later complaint. *Id.* at 1188. The court determined that the earlier complaint constituted a "pending action" because it was pending when the subsequent relator brought her claim and provided the government notice of the basic facts of a fraudulent scheme. *Id.*

Piacentile argues that his complaint cannot be deemed barred at this stage because the Gohil matter may soon be dismissed. (Opp'n Br. at 10–11.) According to Piacentile, "a 'first-filed' complaint will not preempt a later filed complaint if the initial complain fails on jurisdictional grounds or under Rule 9(b)." (Opp'n Br. at 11.) He cites to a handful of cases from other circuits that he claims support his argument. *See United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 516 (6th Cir. 2009) (*Poteet I*), *United States ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 323 (D. Mass. 2009) (*Poteet II*), and *Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 825 (9th Cir. 2005). The better view, however, is the one expressed in *Lujan*: that even complaints that are later dismissed have preclusive effect.

In addition to the cases noted above, Piacentile cites to *United States ex rel. Ortega v. Columbia Healthcare*, 240 F. Supp. 2d 8, 13 (D.D.C. 2003) for the proposition that Rule 9(b)'s requirements limit the preclusive effect of a first-filed complaint. *Ortega*, in turn, cited *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998), which stated that Rule 9(b)'s requirement that "plaintiffs . . . plead fraud with particularity . . . provides sufficient deterrence against overly broad allegations." Notwithstanding the holding in *Ortega*, this Court is satisfied that the Third Circuit's concern in *LaCorte* was with would-be relators bringing unsupported claims merely to preempt others and stake a claim to a *qui tam* windfall. The court did not say that later claimants need not worry about earlier inadequate pleadings; it said that those who file inadequate pleadings will not be rewarded.

The ramifications of providing an exception to the first-to-file rule are highlighted by *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966 (6th Cir. 2005), which is also cited by Piacentile. In *Walburn*, the Sixth Circuit held that a prior filing that is defective under Rule 9(b) has no preclusive effect under the first-to-file rule; it then went on to analyze a pleading then before the District Court of Maryland and find it insufficient under Rule 9(b), and therefore non-preclusive. *Id.* at 972. In a footnote, the Sixth Circuit noted that while the *Walburn* appeal was pending, the Maryland case was dismissed for failure to plead fraud with particularity. *Id.* at 972 n.5. The court stated that it based its decision on the preclusive effect of the Maryland case not on the ultimate outcome, but on its own view of the sufficiency of the Maryland pleading, "because the ultimate fate of an earlier-filed action does not determine whether it bars a later action under § 3730(b)(5); rather, the question is only whether the earlier action was 'pending' at the time the later action was filed." *Id.*

Setting aside the seemingly contradictory nature of the latter statement and the peculiarity of a court opining on the sufficiency of a pleading pending before another court, the Six Circuit's reasoning suggests that even if the Maryland case had been allowed to proceed, it would still have found the Maryland case to have no preclusive effect and would have allowed the *Walburn* action to proceed, as well. Such a result would undermine the first-to-file rule, which serves to prevent repetitive suits once a whistleblower "provides the government notice of the essential facts of an alleged fraud." *Lujan*, 243 F.3d at 1187. The *Walburn* court stated that because the purpose of the pleading requirements of Rule 9(b) is to provide the defendant notice of the fraud alleged, any *qui tam* claim that fails to meet the Rule 9(b) standard would not give the government adequate notice. 431 F.3d at 973. However, the court failed to account for the FCA's unique procedure, under which a complaint is sealed—and not served on the defendant—

for at least 60 days while the government investigates the relator's claims and decides whether to intervene. 31 U.S.C. § 3730(b)(2)–(4); Donald H. Caldwell, Jr., Qui Tam *Actions: Best Practices For Relator's Counsel*, 38 J. Health L. 367 (2005); *cf. LaCorte*, 149 F.3d at 234 (noting that in many cases, a prolonged government investigation may be necessary). After an extensive investigation of a relator's claim, the government is likely to have ample notice of the underlying facts, regardless of whether the complaint is later dismissed.

On its face, § 3730(b)(5) is "exception free." *Lujan*, 243 F.3d at 1187. Because allowing an exception in the event of first-filed claims that may be later dismissed would run counter to the purpose of the first-filed bar, the Court declines to grant an exception in this case.

2. Piacentile's Claims Against Aventis Regarding Anzemet and Taxotere Are Precluded by the First-to-File Bar

Under § 3730(b)(5), a later-filed complaint is barred if it arises "from events that are already the subject of existing suits." *LaCorte*, 149 F.3d at 232. The later case "need not rest on precisely the same facts as a previous claim to run afoul of this statutory bar. Rather, if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details." *Id.* at 232–33. As the Third Circuit noted in *LaCorte*, "duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *Id.* at 234.

The complaint in the Gohil matter alleges the essential facts of the fraudulent scheme Piacentile alleges. Counts Three and Four of the Gohil complaint allege that Aventis distributed to physicians overfilled vials and free samples of Anzemet for which the physicians received reimbursement from the government. (Gohil Complaint, attached to Antonian Certif. as Ex. C, ¶¶ 56–64, 65–76.) Counts Five, Seven, Eight, and Eleven allege that Aventis paid doctors in the

form of money and property, including sham research grants, to induce them to prescribe Anzemet and Taxotere. (*Id.* ¶¶ 77–89, 105–121, 122–134, 179–192.) Count Nine of the Gohil complaint alleges that Aventis sales representatives were instructed to encourage the use of Taxotere for non-approved uses. (*Id.* ¶¶ 135–160.) Count Twelve alleges that Aventis provided valuable services to doctors to assist them in obtaining reimbursement. (*Id.* ¶¶ 193–207.) All of this conduct is also alleged in Piacentile's complain. (Second Am. Compl. ¶¶ 60–83, 85–105, 106–116, 117–124.) Piacentile argues that his complaint provides details about the doctors and hospitals involved in the scheme, the "martini budget" Aventis's sales representatives were given, and the amount of the kickbacks the doctors were given. (Opp'n Br. at 13.) However, this information merely "incorporates somewhat different details" of the scheme and is insufficient to save Piacentile's claims. *See LaCorte*, 149 F.3d at 232–33. Piacentile also contends that his complaint adds state law claims and should not be barred; however, the underlying facts of the alleged scheme remain the same. Therefore, Piacentile's claims against Aventis regarding Anzemet and Taxotere are barred by the first-to-file rule.

B. Piacentile's Complaint Fails to Plead Fraud with Particularity

Even if this Court were to decide that the first-to-file rule did not bar Piacentile's claims against Aventis, those claims, as well as the claims against Sanofi, would nevertheless be dismissed for failure to plead fraud with particularity.

1. Sections 3729(a)(1)–(2)

To state a claim under § 3729(a)(1), a plaintiff must plead three elements: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004)

(*Schmidt I*) (quoting *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001). "In order to prove a claim under § 3729(a)(2), a plaintiff must also show that the defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." *Id.*

FCA claims must be plead with particularity under Rule 9(b). *Id.* n.9 (citing *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998). More specifically, Rule 9(b) commands that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." Fed. R. Civ. P. 9(b). Pursuant to this heightened pleading standard, plaintiffs must "plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Machinery Corp. v. Southmost Machinery Corp.*, 742 F.2d 786, 791 (3d Cir. 1984). This requires a description of the "'who, what, when, where and how' of the events at issue." *In re Rockefeller Ctr. Props. Secs. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002).

While the Third Circuit has not squarely addressed how Rule 9(b) interacts with the elements of claims under §§ 3729(a)(1)–(2)—particularly the requirement that a defendant present or cause to be presented a claim for payment—other courts have. In granting a motion to dismiss, the 11th Circuit, in *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002), held that a plaintiff must plead the existence of at least one specific claim that was submitted to the government. The court stated that

> Rule 9(b)'s directive that "the circumstances constituting fraud or mistake shall be stated with particularity" does not permit a False Claims Act plaintiff merely to

> describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.

Id. Underlying this holding was the court's recognition that without some allegation of the presentment of a false claim to the government, even if a defendant's acts are improper, no damage has been done to the public fisc. *Id.* Relying on *Clausen*, the Third Circuit held in *United States ex rel. Quinn v. Omnicare*, 382 F.3d 432, 440 (3d Cir. 2004) that an FCA action requires the identification of at least one specific claim and that a relator's theory that false claims "must have been" submitted could not survive summary judgment. The *Quinn* court stated that an FCA relator must come to court with a "claim in hand." *Id.* While *Quinn* was decided on summary judgment, the point still stands: "relators must identify with particularity the precise claims submitted to the government that are alleged to be false or fraudulent." *United States ex rel. Schmidt v. Zimmer, Inc.*, 2005 WL 1806502, at *1 (E.D. Pa. July 29, 2005) (*Schmidt II*).

Piacentile points to *Schmidt I* as being very similar to the case at bar and suggests that *Schmidt I* militates toward allowing his action to proceed even without any allegations of a specific false claim. In *Schmidt I*, Zimmer, an orthopedic implant manufacturer, entered into contractual arrangements with hospitals to provide them incentives for ordering Zimmer products. *Id.* at 237. The complaint alleged that approximately 1,600 hospitals were part of Zimmer's scheme, but only named one of them. *Id.*; *Schmidt II*, 2005 WL 1806502, at *1. Piacentile's reliance on *Schmidt I* is misplaced. The Third Circuit's decision in that case held that the relator's complaint against the one named hospital was sufficient under Rule 9(b), but assumed without deciding that the relator's claims against Zimmer were insufficient under Rule 9(b). *Schmidt I*, 386 F.3d at 242 n.9. On remand, the district court confirmed the Third Circuit's

assumption, determining that the alleged fraud was not pleaded with particularity as to Zimmer's contracts with the unnamed hospitals because only an actually submitted claim could connect Zimmer's allegedly illegal marketing campaign to FCA liability, and no claim was even suggested. *Schmidt II*, 2005 WL 1806502, at *3. In contrast, it was clear that the named hospital had submitted at least one claim because, as the court noted, the hospital was required to submit annual cost reports to the government in order to reconcile its costs with the government funds it received. *Schmidt I*, 386 F.3d at 237.

Other courts have stated that "where the alleged false claims were submitted not by the defendant, but by a third party instead, . . . the relator need not allege the details of particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA,'" *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 390 (D. Mass. 2008) (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 732 (1st Cir. 2007)); *see also Underwood*, 720 F. Supp. 2d at 679. Even under this more lenient standard, a relator must provide particular details "of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted," *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009), and on this basis, Piacentile's complaint still fails.

Piacentile claims that Aventis and Sanofi promoted their drugs off-label and paid kickbacks to doctors in the form of free drug samples, overfilled prescriptions, educational grants, and speaker's fees. Yet his allegations of the claims that were submitted to the government are conclusory, as are his allegations that the doctors actually prescribed Aventis's and Sanofi's drugs off-label to patients covered by government health programs. For example, Piacentile claims that "Aventis's aggressive marketing of the off-label uses of Taxotere to treat

prostate cancer and early stage breast cancer caused prescriptions for Taxotere to be written based upon that off-label marketing, and consequently caused false claims to be submitted to Medicaid and other government health programs." (Second Am. Compl. ¶ 72.) He also states that on each occasion where Aventis or Sanofi either promoted their drugs off-label or paid a kickback and a doctor prescribed those drugs, a false claim was submitted. (*Id.* ¶¶ 78, 100, 104, 115, 122, 130, 134, 147.) Piacentile identifies doctors whom he claims received speaker's fees, including Drs. Paula Kline, Clifford A. Huddis and Naiyer A. Rizvi, and then states that when those doctors and the doctors who attended their presentations sought reimbursement from the government for Taxotere, false claims were submitted. (*Id.* ¶¶ 82, 83.) Yet the only allegation that any of these doctors actually prescribed Taxotere states that "Dr. Huddis played a central role in boosting Sloan Kettering's purchases of Taxotere from 170 vials a month to as many as 400 vials a month, mostly for off-label use." (*Id.* ¶ 94.) The complaint makes no mention of how Piacentile knows these vials were used off-label, but baldly states that they were. The complaint also baldly states that the overfilled prescriptions Aventis provided to physicians resulted "in the physicians' billing the government for an additional 100 or more vials per month." (*Id.* ¶ 109.) Tellingly, the complaint alleges that "[t]hese additional drugs, like the free drug samples, *could* be billed by the physicians or medical institutions to a government-funded insurer for full reimbursement . . . ," but does not allege that they actually were. (*Id.* (emphasis added).) Other allegations that certain doctors increased their use of Aventis and Sanofi drugs are similarly conclusory. (*Id.* ¶¶ 113, 140.)

In sum, the complaints allegations are inadequate to provide the who, what, when, where and how of the defendants' alleged fraud and do not place them on notice of the exact

misconduct with which they are charged. Therefore, Piacentile's claims under §§ 3729(a)(1)–(2) are dismissed.

2. Section 3729(a)(3) and (a)(7)

To allege a conspiracy under § 3729(a)(3), a plaintiff must plead "(1) that the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States; (2) that one or more of the conspirators performed any act to effect the object of the conspiracy; and (3) that the United States suffered damages as a result of the false or fraudulent claim." *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Provident Life & Acc. Ins. Co.*, 721 F. Supp. 1247, 1259 (S.D. Fla. 1989). "The essence of a conspiracy under the Act is an agreement between two or more persons to commit a fraud." *Id.*

Under § 3729(a)(7), a plaintiff must plead a "reverse false claim." The complaint must allege that "the defendant made or used (or caused someone else to make or use) a false record in order to avoid or decrease an obligation to the federal government." 386 F.3d at 242. "The plaintiff must prove that the defendant did not pay back to the government money or property that it was obligated to return." *Quinn*, 382 F.3d at 444. This means that the defendant must have had an existing legal obligation to give money or property to the government. *Kennard v. Comstock Resources, Inc.*, 363 F.3d 1039, 1048 (10th Cir. 2004). As with all claims under the FCA, conspiracies and reverse false claims must be pleaded with particularity. *Palladino ex rel. United States v. VNA of S. N.J., Inc.*, 68 F. Supp. 2d 455, 462 (D.N.J. 1999); *United States ex rel. Vallejo v. Investronica, Inc.*, 2 F. Supp. 2d 330, 336 (W.D.N.Y. 1998).

In this case, the complaint fails to plead the alleged conspiracy and the alleged reverse false claim with particularity. Significantly, Piacentile has failed to allege any meeting of the minds between the defendants and the doctors who prescribed their drugs. In his opposition

brief, he does not refer the Court to any portion of the complaint that alleges an agreement with particularity; he merely cites to references to doctors who received speaker's fees and other purportedly improper benefits. (Opp'n Br. at 22.) Furthermore, he does not allege any existing obligation on the part of the defendants, and in his opposition brief, he states, without any analysis, that Third Circuit precedent supports his position. (Opp'n Br. at 23.) For the foregoing reasons, Piacentile's claims under §§ 3729(a)(3) and (a)(7) are dismissed.

3. A Relaxed Pleading Standard Is Not Available to Piacentile

Piacentile argues that he is entitled to a relaxed standard for pleading fraud because factual information regarding claims that have been submitted to the government is within the defendants' knowledge or control. "Where it can be shown that the requisite factual information is peculiarly within the defendant's knowledge or control, the rigid requirements of Rule 9(b) may be relaxed." *United States ex rel. Monahan v. Robert Wood Johnson Univ. Hosp. at Hamilton*, 2009 WL 1288962, at *5 (D.N.J. May 7, 2009). In order to reap the benefit of a relaxed standard, a plaintiff must allege that the information lies exclusively in the defendants' control. *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 285 (3d Cir. 1992). Moreover, a plaintiff "must accompany such an allegation with a statement of facts upon which their allegation is based." *Id.* In any event, if a third party or the government possesses information that plaintiffs allege is held by the defendants, relaxing the Rule 9(b) standard is inappropriate. *In re Tellium Inc., Sec. Litig.*, 2005 WL 1677467, at *13 (D.N.J. June 30, 2005). In *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 308–09 (5th Cir. 1999), the Fifth Circuit declined to relax Rule 9(b) where information was possessed by third parties, including the Healthcare Financing Administration, which was the precursor to the current agency that processes federal government health care reimbursements. As in *Russell*, the federal government

would possess information regarding claims filed by the doctors and institutions listed in Piacentile's complaint, as would the doctors themselves. Moreover, Piacentile has not alleged any facts in support of his claim that the defendants exclusively possess material information. Instead, he uses boilerplate language. (Second Am. Compl. ¶¶ 84, 124, 131, 151.) Piacentile is therefore not entitled to a relaxed pleading standard.

III. Conclusion

With Piacentile's federal claims dismissed, the only remaining claims are those brought under the various state false claims acts. The Court declines to exercise jurisdiction as to those claims, and Piacentile's Second Amended Complaint is therefore dismissed. 28 U.S.C. § 1367; *see also United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 726 (1966) ("Certainly, if the federal claims are dismissed before trial, even though not insubstantial in a jurisdictional sense, the state claims should be dismissed as well.").

/s/ Katharine S. Hayden

December 31, 2010 Katharine S. Hayden, U.S.D.J.